Site visit inspection report on compliance with HTA minimum standards

Queen Victoria Hospital

HTA licensing number 11091

Licensed for the

- **procurement, processing, testing, storage, distribution and import of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended); and**

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

10 – 11 October 2018

Summary of inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Although the HTA found that the Queen Victoria Hospital (the establishment) had met the majority of the HTA standards, five minor shortfalls were found in relation to governance and quality system standards and premises, facilities and equipment standards. The HTA has also given advice to the Designated Individual with respect to staff training, audits, tissue labelling and temperature monitoring.

The shortfalls relate to the systems used to ensure that imported tissue meets the standards of quality and safety set out in Directions 002/2018, recording of the Single European Code, the requirement to report SAEARS within 24 hours of discovery, the security of the premises and environmental monitoring of the tissue processing environment.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Ocular; Cornea	**E**	**E**	**TPA**	**E**	**E**	**E**	
Other; Limbal Stem Cells (ATMP)	**E**		**TPA**				
Other; Oral Epithelial (ATMP)	**E**		**TPA**				
Membrane, Amniotic; Amniotic Membrane				**E**			
Skin; Skin				**E**			

Background to the establishment and description of inspection activities undertaken

The establishment is licensed for the procurement, processing, testing, storage, distribution and import of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Regulations). It is also licensed under the Human Tissue Act 2004 (HT Act) for the storage of relevant material which has come from a human body for use for a scheduled purpose. However, at the time of the inspection, although relevant material was being stored for use in research, this was all being held under recognised research ethical approval and not under the authority of the establishment's licence.

The establishment has been licensed by the HTA since November 2006 and this was the sixth routine site visit inspection and the first since the amended Quality and Safety Regulations came into force on 1 April 2018 to implement the import and coding directives. The inspection focused separately on imported tissue and tissue procured by the establishment itself or supplied to the establishment by other HTA-licensed establishments.

The purpose of the inspection was to assess whether or not the establishment continues to meet the HTA standards. Annual activity data, pre-inspection discussions with the DI and the previous inspection report were used to inform the timetable that was developed for this inspection.

Imported Tissue

The establishment imports tissues from two separate third country suppliers (3CS) which are outside of the European Economic Area. The first supplier provides a proprietary tissue product used for ocular surgery. This tissue is supplied to the establishment who stores and distributes the tissue to end users. Currently, the tissue is only used as part of a clinical trial with only one trial site to date receiving tissue for end use; however, other trial centres will open in the future. Upon receipt of the tissue, establishment staff review the donor serology and verify that the transport packaging is intact as part of the tissue receipt procedure. The tissue supplier provided blank donor medical history questionnaires (used by the tissue retrieval organisation from whom tissue for processing into the end product originates) for review in addition to details of serological testing and terminal sterilisation for one unit of the processed tissue product.

A second supplier provides corneas to the establishment for either end use at the establishment's Trust or distribution to other centres for end use. Tissue is ordered as it is required so that it arrives just before the planned surgery date. Upon receipt of the tissue, establishment staff review the donor serology and verify that the transport packaging is intact as part of the tissue receipt procedure. All corneas received by the establishment from the supplier are recorded in the establishment's electronic database and have a Single European Code (SEC) added to them by the establishment to aid traceability. As part of the inspection, the inspection team reviewed blank donor selection/medical questionnaires and donor serology testing results, in addition to records of receipt and traceability maintained by the establishment in the electronic database for three corneal donors.

Corneas (procured by the establishment)

The establishment also procures and processes corneas for its own use and for distribution to other centres for end use. Potential donors are referred to the establishment either directly or via the national tissue donor referral centre. Establishment staff contact the donor's family and seek consent from an appropriate person before reviewing the donor's medical history in order to establish the suitability of the donor. Donor testing is carried out under an appropriate third party agreement. Corneas are processed at the establishment within a clean room environment. All establishment staff working within the clean room undergo training to work in the clean room with six monthly gowning re-validation. In addition, each member of staff carries out a simulated process every six months to verify that they continue to work appropriately within the clean room. Prior to being issued for end use, the donor records, including the medical/social history and serological testing results, are reviewed. The review also incorporates the cornea's cell count, microbiological testing results and environmental monitoring results. These reviews are carried out by the DI who, if all are satisfactory, authorises the tissue for release. Although the donor medical/social history is reviewed, this review is not recorded as one of the pre-release checks (see advice item 4).

Some procured corneal tissue is used as a starting material for an Advanced Therapy Medicinal Product (ATMP). Limbal epithelial stem cells (LSCs) are isolated from the corneo-scleral region of the donated eye and expanded in culture to produce the ATMP. In relation to ATMP production, the donor selection, consent, procurement and donor testing is undertaken under the Regulations; however, processing takes place under the regulatory remit of the Medicines and Healthcare products Regulatory Agency (MHRA).

Corneas can also be pre-cut for Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK) cases. Pre-cutting is carried out in the Eye Bank using a microkeratome and single use instruments.

Processed corneas that do not meet the requisite cell count are transferred into alcohol and stored for up to twelve months for potential use in eye preservation treatments for conditions such as glaucoma.

Oral mucosal ATMP

The establishment also procures mucosal tissue as a starting material for an ATMP. The ATMP is used autologously and, as above, the establishment undertakes donor selection, consent, procurement and donor testing under the Regulations with processing taking place under the regulatory remit of the MHRA.

Other tissues

The establishment also purchases frozen amniotic membrane and frozen skin from other HTA-licensed establishments. Tissue is received by the establishment, recorded in the establishment's electronic database and stored in an appropriately monitored -80^{o}C freezer prior to use.

Audit exercise

During the inspection audits were carried out for two corneas procured by the establishment, DSAEK tissue, corneas stored in ethanol, frozen skin and frozen amniotic membrane.

In relation to the corneas retrieved by the establishment, the consent form, medical/social history, risk assessment of the retrieval site, donor serological testing results, GP medical history, tissue sterility results, records of consumables and reagents used during retrieval and

processing, environmental monitoring data and the final batch release/authorisation for release forms were reviewed for two donors of three corneas. No anomalies were identified.

Records for a cut cornea for DSAEK were also reviewed as above and additionally the records relating to the processing of the cut tissue were reviewed. No anomalies were identified.

Records for a cornea that had been stored in ethanol were reviewed. No anomalies were identified.

Records from one pack of frozen skin were reviewed. The location in the establishment's freezer was cross-checked against the details held in the establishment's electronic database, including records of receipt. When reviewing the database, an example of a unit of skin was found where the Single European Code had not been recorded.

Records relating to one unit of amniotic membrane held in the establishment's freezer were reviewed. Location details of the tissue were cross-checked against the details held in the establishment's electronic database, including records of receipt. The database was also reviewed for records of receipt and issue of amnion. All of the amniotic membrane is generally used by the establishment and no record of the SEC is maintained. An example of where an amniotic membrane had been distributed to another establishment for use without the Single European Code of the tissue product being recorded by the establishment was identified during this review.

Finally, a consent record for oral mucosal tissue from one donor was also reviewed.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
n) The establishment ensures imports from non-EEA states meet the standards of quality and safety set out in Directions 002/2018.	The establishment has agreements with the exporters of tissue products received by the establishment and donor virology results are reviewed upon receipt of imported tissue. However, there are no other mechanisms in place such as audits of donor selection and reviews of testing results to assure the DI that imports from non-EEA states meet the standards of quality and safety set out in Directions 002/2018. In addition, prior to the inspection, upon requesting the environmental monitoring data form a third country supplier the DI found that environmental monitoring as required by the Regulations was not being carried out during the processing of the pre-cut tissue. As a result the establishment no longer imports any pre-cut tissue and only receives whole corneas from this supplier. Instances where imported tissue that did not meet the standards of quality and safety set out in Directions 002/2018 and have been used in treatments have been reported to the HTA as serious adverse events and will be followed up in accordance with the HTA's adverse events procedures.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	During the audit of tissue purchased from another HTA licensed establishment, an example of an amniotic membrane being distributed to another establishment without the Single European Code of the tissue product being recorded by the establishment was identified.	**Minor**

GQ7 There are systems to ensure that all adverse events are investigated promptly.		
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.	Some of the establishment's end user agreements stipulate that serious adverse events and reactions (SAEARs) must be reported to the establishment 'immediately' as opposed to the required reporting period of within 24 hours of identification of the event or reaction.	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE1 The premises are fit for purpose.		
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.	The establishment is located within a building which is also used for various Trust meetings, including some with non-Trust staff in attendance. Between the two parts of the building where meetings are held and the establishment's premises are located is a door which is unlocked. The establishment has commenced work to have a magnetic lock attached to this door, which can be automatically opened in the case of emergency. However, the work is not complete meaning the door cannot be secured. There is currently a potential risk that an unauthorised person may access the establishment.	**Minor**
PFE2 Environmental controls are in place to avoid potential contamination.		
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 002/2018.	Pressure readings for the clean room are recorded daily Monday to Friday irrespective of any processing taking place; however, records of pressure readings are not made during weekends.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.	The establishment does process corneas during some weekends and therefore, pressure readings from the clean room facility must be taken and recorded during	

h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	weekends when processing is taking place, to assure the clean room operatives that the facility is functioning as expected. In addition, the establishment undertakes environmental monitoring for fungal contaminants on a weekly basis and not during other tissue processing steps which involve exposure to the environment.	

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C3(a)	Establishment staff involved in the seeking of consent have received training. In addition to this training, the DI is advised to organise establishment staff to develop a system through which staff assess each other's consent seeking practice and/or to offer external refresher training in the seeking of consent. This may help to assure the DI that establishment staff follow the establishment's procedures and best practice when seeking consent.
2.	GQ1(d)	The establishment has secured funding for an electronic governance and quality system which it is envisaged will be used to store procedural documents and used to track audits, risk assessments and incidents. The DI is advised to continue with the plans to implement this system as it may facilitate some of the governance functions currently carried out by the DI manually.
3.	GQ2(b)	The DI is advised to increase the frequency of audits relating to the establishment's records and raw data. In addition, the DI is advised to continue with plans to introduce observational audits for staff undertaking licensable activities. Some observational audits take place during training and competency assessments of new staff. However, the DI could expand such audits to all staff to help assure himself that establishment staff continue to work in accordance with the establishment's procedures.
4.	GQ5(d)	During final review of cornea-related data prior to authorising the tissue as suitable for release and use, a batch release form is completed. This form includes a checklist to record that serology testing results, cell count, microbiological screening results, tissue storage and environmental monitoring data are suitable. The DI is advised to add a space to record that the donor medical and social histories were also reviewed and the results of this review.
5.	GQ6(d)	The manufacturer of the tissue product being imported for use in clinical trials has extended the shelf life of the tissue product and has issued new labels for the product boxes. The DI is advised to not overlay the new product label over the existing label. The DI is advised to mark the existing label so that it is clear it is void but remains readable and attach the new label in a new area of the box.
6.	PFE4(g)	The tissue product being imported for use in clinical trials has an acceptable temperature range of $2^{o}C$ – $30^{o}C$ during transport to the establishment. However, the tissue units do not have a stipulated temperature range for storage. The DI is advised to contact the manufacturer to ascertain any temperature requirements during the storage of the product and if applicable to

		implement a suitable temperature monitoring system.

Concluding comments

A number of areas of practice were identified during this inspection that require improvement, resulting in five minor shortfalls. The shortfalls related to the systems used to ensure that imported tissue meets the standards of quality and safety set out in Directions 002/2018, recording of the Single European Code, the requirement to report SAEARS within 24 hours of discovery, the security of the premises and environmental monitoring of the tissue processing environment. The HTA has also given advice to the Designated Individual with respect to staff training, audits, tissue labelling and temperature monitoring.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 15 November 2018

Report returned from DI: No comments received

Final report issued: 18 December 2018

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions Directions 002/2018 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured,

processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.

c) The premises have sufficient space for procedures to be carried out safely and efficiently.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 002/2018.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 002/2018.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.

h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 Standards

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.
c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.
e) Language translations are available when appropriate.
f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.
b) Records demonstrate up-to-date staff training.
c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.
b) There is a document control system.
c) There are change control mechanisms for the implementation of new operational procedures.
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities.
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed

by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.